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Intellectual Property Department Amylin Pharmaceuticals, Inc. 9360 Towne Centre Drive San Diego, CA 92121			HEARD, THOMAS SWEENEY	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LESLIE PHILIP MIRANDA and STEPHEN B. H. KENT

Appeal 2010-007239
Application 10/541,078
Technology Center 1600

Before TONI R. SCHEINER, DONALD E. ADAMS, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

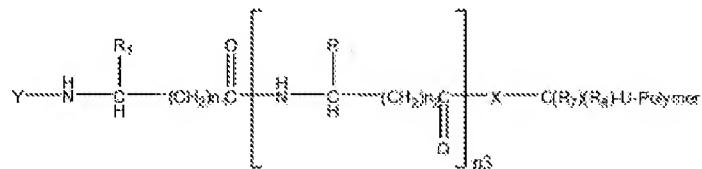
DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a water-soluble thioester or selenoester compound. The Patent Examiner rejected the claims as failing to comply with the written description requirement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 60-72 are on appeal. Claim 60 is representative and reads as follows:

60. A water-soluble thioester or selenoester compound of the formula:



wherein Y is selected from the group consisting of: an amino acid, a peptide, and a polypeptide;

X is sulfur or selenium;

n_1 and n_2 are each from 0 to 2, and n_3 is from 0 to 100;

R and R₁ are individually selected from the group consisting of: hydrogen, a side chain of an amino acid, a branched alkane, a cycloalkane, an alkyl-substituted aryl or heteroaryl group, and combinations thereof;

R₇ and R₈ are each, individually, selected from hydrogen, substituted and unsubstituted linear or branched chain alkyl, aryl, heteroaryl and benzyl;

U is a linker or spacer and may be present or absent and, when present, consists of a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms;

Polymer is a water-soluble polymer of a formula selected from the group consisting of: $-\left[\text{C}(\text{O})-\varphi-\text{C}(\text{O})-\text{NH}-\psi-\text{NH}\right]n_5$ and $-\left[\text{NH}-\psi-\text{NH}-\text{C}(\text{O})-\varphi-\text{C}(\text{O})\right]n_5$, where n_5 is an integer from 2 to 100, and

φ and ψ are divalent radicals that may be the same or different and are selected from the group consisting of $-((\text{CH}_2)n_6-(\text{CH}_2\text{CH}_2\text{O})n_7-(\text{CH}_2)n_6-)$ and $-((\text{CH}_2)n_6-(\text{O}-\text{CH}_2\text{CH}_2\text{O})n_7-(\text{CH}_2)n_6-)$, where n_6 is an integer from 1 to 6 and n_7 is an integer from 2-50, and where φ can also be $-(\text{CH}_2-\text{CH}_2)-$ and ψ can also be $-(\text{CH}_2-(\text{CH}_2-\text{CH}_2-\text{O})_3-\text{CH}_2-\text{CH}_2-\text{CH}_2)-$ or $-(\text{CH}_2-\text{CH}_2-\text{CH}_2-(\text{O}-\text{CH}_2-\text{CH}_2)_3-\text{CH}_2)-$.

The Examiner rejected claims 60-72 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

WRITTEN DESCRIPTION

The Issue

The Examiner's position is that the Specification "fail[ed] to provide adequate written description for the genus of claims and does not reasonably convey to one skilled in the art the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention." (Ans. 8.) According to the Examiner, although the Specification provided written description for two examples, "there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed." (*Id.* at 7.) In particular, the Examiner found that the variables R_1 , R_7 , R_8 , and variance in n_1 , n_2 , n_3 and the polymer do "not allow for a core structure to inform one of ordinary skill in the art as [to] what is to be made." (*Id.*)

Appellants contend that that "a specific and limited core structure is provided in independent claim 60 with [] reasonably limited constituents attached to that core...." (App. Br. 8.) Additionally, Appellants assert that the Specification's Examples 2-6 present an actual reduction to practice the claimed invention, which also satisfies the written description requirement. (*Id.* at 10.) Further, Appellants assert that a written description of the claimed invention is provided by the Specification's description of the "structure 13," i.e., the structure of a thioester water-soluble polymer. (*Id.* at 11.) According to Appellants, because these disclosures "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant[s were] in possession of the invention as claimed, the written description requirement is satisfied." (*Id.* at 13.)

The issue with respect to this rejection is whether the Examiner established that a person of ordinary skill in the art would not credit Appellants with possession of the claimed invention.

Principles of Law

In order to satisfy the written description requirement, “the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

“One shows that one is ‘in possession’ of *the invention* by describing *the invention*, with all its claimed limitations.... One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

Analysis

We agree with Appellants that a skilled artisan at the time of filing would have understood that Appellants were in possession of the claimed invention. Independent claim 60 provides the structural formula for the compound as well as defining each variable comprising that formula. (See App. Br. 14, Claims App’x.) “One shows that one is ‘in possession’ of *the invention* by . . . such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572. The critical factual question is whether the formula claimed was described in the Specification. The rejection instead concerns itself with whether the description “would allow one of skill in the

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art to practice the invention as claimed" (Ans. 7), and "what has been reduced to practice and exemplified" (*id.*). Neither of those concerns shows that the formula set out in claim 60 was not described in the Specification.

CONCLUSION

The Examiner has not established that a person of ordinary skill in the art would not credit Appellants with possession of the claimed invention.

SUMMARY

We reverse the rejection of claims 60-72 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

REVERSED

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